IN THE DRAWINGS:

The attached sheet of drawings includes changes to drawing sheet 5/17. This sheet now labeled as Fig. 5, replaces the original sheet 5/17 labeled as Fig. 1.

IN THE CLAIMS

1. (Currently amended) A method for controlling the growth and/or development of a cancer in an animal or avian species, said method comprising administering to said animal or avian species ~~an effective amount of~~ a phospholipase inhibitor in an amount effective to reduce the level or activity of a phospholipase, wherein said phospholipase inhibitor comprises the amino acid sequence set forth in SEQ ID NO:1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1 ~~or a functional derivative or homologue thereof~~.

2. (Currently amended) ~~A~~ The method according to claim 1 wherein the phospholipase inhibitor ~~or derivative or homologue~~ reduces the ~~levels and/or activities~~ level or activity of ~~a~~ the phospholipase to an extent to reduce the growth and/or development of cancer cells.

3. (Currently amended) ~~A~~ The method according to claim 1 wherein the growth and/or development of cancer is in an animal.

4. (Currently amended) ~~A~~ The method according to claim 3 wherein the animal is a human.

5. (Currently amended) ~~A~~ The method according to claim 1 wherein the phospholipase inhibitor reduces the volume of cancer in the animal or avian species.

6. (Currently amended) ~~A~~ The method according to claim 1 wherein the phospholipase inhibitor inhibits more than one type of phospholipase type A_2 (PLA_2).

7. (Currently amended) ~~A~~ The method according to claim 6 wherein the PLA_2 inhibitor is ~~derived from~~ of a *Notechis scutatus* or *Notechis ater* origin.

8. (Currently amended) ~~A~~ The method according to claim 7 wherein the PLA_2 inhibitor comprises ~~an~~ the amino acid sequence ~~substantially~~ set forth in SEQ ID NO:1 ~~or any one of SEQ ID NOs:4 to 11 or 12 to 33~~.

9. (Canceled)

10. (Previously presented) A method according to claim 1 wherein the phospholipase inhibitor inhibits secretory PLA_2 which in turn reduces expression of COX2 thereby reducing catalytic conversion of arachidonic acid to prostaglandin.

11. (Currently amended) A biological composition useful for the treatment and/or prophylaxis of cancer in a target animal or bird such as a human, primate, livestock animal or companion animal said composition comprising a PLA_2 inhibitor, wherein said phospholipase inhibitor comprises the amino acid sequence set forth in SEQ ID NO:1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1 ~~such as but not limited to the PLA_2 defined by any one of amino acids sequences set forth in SEQ ID NOs: 1 to 11 or 12 to 33 or a derivative, homologue, analogue or functional equivalent thereof~~.

12. (Currently amended) A method for controlling the growth and/or development of a cancer in an animal or avian species, said method comprising administering to said animal or avian species ~~an effective amount of~~ a PLA_2 inhibitor ~~having an amino acid sequence substantially as set forth in any one or more of SEQ ID Nos: 1 to 11 or 12 to 33 or an amino acid sequence having at least 60% identity to any one or more of SEQ ID NOs: 1 to 11 or 12 to 33 or a functional derivative or homologue thereof which PLA_2 inhibitor or derivative or homologue reduces~~ in an amount effective to reduce the level or activity of secretory PLA_2 thereby reducing expression of a genetic sequence encoding a cycloxygenase or reducing cycloxygenase activity, wherein said PLA_2 inhibitor comprises the amino acid sequence as set forth in SEQ ID NO: 1 or an amino acid sequence having at leas 60% identity

to SEQ ID NO: 1.

13. (Currently amended) A biological composition useful for the treatment and/or prophylaxis of cancer in a target animal or bird, ~~such as a human, primate, livestock animal or companion animal~~ said composition comprising a PLA_2 inhibitor which comprises the amino acid sequence as set forth in SEQ ID NO: 1 or an amino acid sequence having at leas 60% identity to SEQ ID NO: 1 ~~such as but not limited to the PLA_2 defined by any one of amino sequences set forth in SEQ ID NOs: 1 to 11 or 12 to 33 or a derivative, homologue, analogue or functional equivalent thereof~~.

14. (New) The composition of claim 13, wherein said animal is selected from a human, primate, livestock animal or companion animal.

REMARKS

In the Office Action dated March 27, 2003, claims 1-13 are pending. Claim 9 is withdrawn from consideration as drawn to a non-elected embodiment. Claims 1-8 and 10-13 are examined to the extent that these claims read on elected SEQ ID NO: 1. Claims 1-8, 10-13 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 1-8 and 10-13 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to meet the written description requirement. Claims 1-8 and 10-13 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enabling support. Claims 1-8, and 10-13 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Wells et al. (WO 97/35588). Claims 1-8 and 10 are further rejected under 35 U.S.C. §102(a) as allegedly anticipated by Prendergast et al. (WO 98/10776). The Examiner also objects to the drawings for certain alleged informalities.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

With respect to the drawings, the Examiner requests Applicants to submit new drawings to correct the error in drawing sheet "5/17" because Figure 5/17 is incorrectly labeled as "Figure 1".

Applicants are providing herewith a substitute Figure 5/17, which is labeled as "Figure 5". No new matter is introduced. Withdrawal of the objection is therefore respectfully requested.

With respect to the claims, claim 9 is withdrawn from consideration as drawn to a

non-elected embodiment. Claims 1-8 and 10-13 are examined to the extent that these claims read on elected SEQ ID NO: 1.

Applicants have canceled claim 9 without prejudice. Claims 1-8 and 10-13 have also been amended to more clearly delineate the elected embodiments. Applicants reserve the right to pursue the non-elected embodiments in a divisional application.

Claims 1-8 and 10-13 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. More specifically, the Examiner objects to the term "effective amount" in claims 1 and 12, the terms "derivative" and "homologue" in claims 1 and 11-13, the term "reduce" in claims 2, 5 and 10, the term "phospholipase inhibitor" in claims 1-8 and 10-13, the term "derived" in claim 7, the term "substantially" in claims 8-9, and the term "such as" in claims 11-13.

In response, Applicants have amended the claims by replacing the term "an effective amount" with "an amount effective to reduce the level and/or activities of a phospholipase". Applicants have also deleted terms "derivative", "homologue", "substantially" and "such as" from the claims. Moreover, the term "derived from" has been replaced with the term "of an ..... origin".

As to the term "reduce", the Examiner contends that the specification has not provided a base level from which the amount of reduction is measured. Applicants respectfully submit that in light of the specification, the meaning of the term "reduce" is clear to those skilled in the art, and that the level and activity of a phospholipase after administration of the inhibitor are being compared to (and are reduced relative to) the level and activity of such phospholipase prior to administration of the inhibitor.

As to the term "phospholipase inhibitor", the Examiner contends that it is unclear as to what this term is intended to encompass. Applicants respectfully submit that the claims, as presently amended, clearly delineate the phospholipase inhibitor as comprising the amino acid sequence set forth in SEQ ID NO:1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1. Thus, the term "phospholipase inhibitor" is not indefinite.

The Examiner also alleges that claims 1-8 and 10-13 are incomplete for omitting essential steps, such as the amount and time of administration, and the regimen in which the inhibitor is used.

Applicants respectfully submit that a principal feature of the present invention resides in the recognition that administration of a phospholipase inhibitor, e.g., an inhibitor comprising SEQ ID NO: 1, can reduce the growth and development of cancer. The claimed methods all recite this feature. Applicants submit that the precise amount and time of administration can be determined by those skilled in the art without undue experimentation in light of the present teachings, and are not necessary to be included in the claims.

In view of the foregoing, it is respectfully submitted that the claims, as presently amended, are not indefinite. Withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is therefore respectfully requested.

Claims 1-8 and 10-13 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to meet the written description requirement. The Examiner admits that the written description in this case has set forth an inhibitor having SEQ ID NO: 1. However, the Examiner contends that there is no disclosure, beyond the mere mention, of derivatives, homologues or functional equivalents of SEQ ID NO: 1, or proteins having at least 60%

identity to SEQ ID NO: 1.

Applicants respectfully submit that the terms "derivative", "homologue" and "functional equivalent" have been deleted from the claims. The claims, as presently recited, are drawn to methods of administration of a phospholipase inhibitor which comprises the amino acid sequence set forth in SEQ ID NO:1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1. The phospholipase inhibitor which is administered is characterized both structurally in terms of its sequence, and functionally as a phospholipase inhibitor. It is respectfully submitted that the claims, as presently recited, fully satisfy the written description requirement of 35 U.S.C. §112, first paragraph. Therefore, withdrawal of the rejection under the written description requirement of 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1-8 and 10-13 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enabling support. The Examiner states that the specification is enabling for a method of reducing the growth of a solid tumor, or a method in the reduction of the cancer (adenocarcinoma or carcinoma) growth in cells expressing elevated levels of PLA2, which method comprises the administration of SEQ ID NO: 1. However, the Examiner contends that the specification does not reasonably provide enablement for a method of controlling the growth or development of any and all cancers with any and all types of phospholipase inhibitors.

Applicants respectfully submit that the presently claimed methods do not employ any and all types of phospholipase inhibitors for controlling the growth and/or development of a cancer in an animal or avian species. Rather, the claimed methods employ a phospholipase

inhibitor which comprises the amino acid sequence set forth in SEQ ID NO:1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1. Applicants further respectfully submit that the specification demonstrates that administration of a phospholipase inhibitor having the amino acid sequence of SEQ ID NO: 1 reduced the growth and development of adenocarcinoma and carcinoma. See, e.g., pages 43-47 of the specification. In light of the present teaching, those skilled in the art would be able to practice the claimed methods with respect to other types of cancers, using a phospholipase inhibitor having the amino acid sequence of SEQ ID NO: 1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1, without undue experimentation. As such, it is respectfully submitted that the rejection under the enablement requirement of 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1-8, and 10-13 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Wells et al. (WO 97/35588). The Examiner alleges that Wells et al. disclose a method of treating cancer comprising the administration of a phospholipase inhibitor to a patient, as well as a composition comprising the phospholipase inhibitor in the presence of a pharmaceutically acceptable carrier.

Applicants respectfully submit that the phospholipase inhibitor disclosed by Wells et al. is an antiserum raised against snake venom. Wells et al. do not teach any phospholipase inhibitor having the amino acid sequence of SEQ ID NO: 1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1. Nor do Wells et al. teach the use of such phospholipase inhibitor in the treatment of cancer. Therefore, Wells et al. do not teach the presently claimed. Withdrawal of the rejection under 35 U.S.C. §102(b) based on Wells et al.

is respectfully requested.

Claims 1-8 and 10 are further rejected under 35 U.S.C. §102(a) as allegedly anticipated by Prendergast et al. (WO 98/10776). The Examiner alleges that Prendergast et al. disclose a method of treating neoplasmia in a human subject, as well as a pharmaceutical composition that comprises one or more inhibitors of a phospholipase.

Applicants respectfully submit that the phospholipase inhibitor disclosed by Prendergast et al. is selected from a group of small organic compounds. Prendergast et al. do not teach any phospholipase inhibitor having the amino acid sequence of SEQ ID NO: 1 or an amino acid sequence having at least 60% identity to SEQ ID NO: 1, let alone the use of such phospholipase inhibitor in the treatment of cancer. Therefore, Prendergast et al. do not teach the presently claimed invention. Withdrawal of the rejection under 35 U.S.C. §102(b) based on Prendergast et al. is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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FSD/XZ:ab
Encl. Replacement Sheet
Annotated Sheet Showing Changes

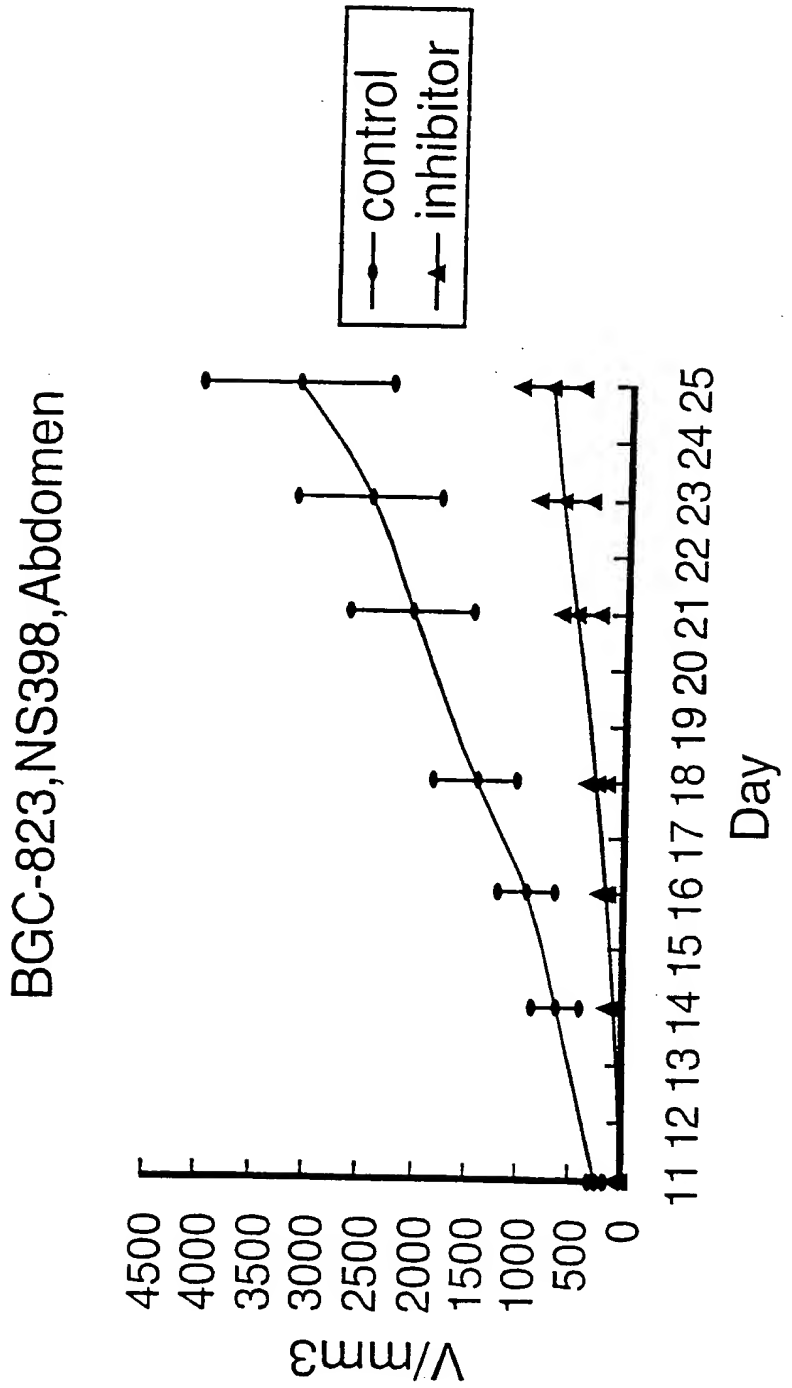

Figure 1/5